

*Rec'd 9/26/05  
ZB*

**Premarket Approval (PMA) Package for  
Dockets Management Branch**

**PMA Number P040037  
Docket # 2005M-0379**

**W.L. Gore & Associates, Inc.  
GORE BIABAHN® Endoprosthesis**

**Includes:**

**Approval Order  
Summary of Safety and Effectiveness Data (SSED)  
Labeling**